

## Message Text

UNCLASSIFIED

PAGE 01 STATE 222429  
ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 EB-08 COME-00 FTC-01  
STR-05 TRSE-00 /040 R

DRAFTED BY DHEW/FDA: JRWEINROTH,M.D.:CM

APPROVED BY O S/A T/BMP:WJWALSH, I

DHEW/PHS/OASH/OIH: RFISCHER

EUR/NE:JSHUMATE (INFO)

EUR/NE:RWOODS (INFO)

-----123996 170435Z /14

R 161323Z SEP 77  
FM SECSTATE WASHDC  
TO AMEMBASSY STOCKHOLM  
AMEMBASSY LONDON

UNCLAS STATE 222429

E.O. 11652: N/A

TAGS: OGEN, OTRA, ETRD, EIND, TBIO, SW, UK

SUBJECT: FDA REPRESENTATIVE PROVIDING TECHNICAL AND  
CONSULTATIVE ASSISTANCE TO FOREIGN DEVICE MANUFACTURERS

1. FDA ADVISES THAT MR. ANTHONY WOLK, ENGINEER, OFFICE OF  
THE EXECUTIVE DIRECTOR OF REGIONAL OPERATIONS WILL BE IN  
EUROPE OCTOBER 15-30, 1977.

2. MR. WOLK WILL VISIT 2 DEVICE MANUFACTURERS TO DETERMINE  
IF THEIR FACILITIES AND OPERATIONS ARE IN ACCORDANCE WITH  
CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS AND WILL  
REPORT ANY SIGNIFICANT DEVIATIONS WHICH WOULD HAVE AN  
ADVERSE EFFECT UPON THE SAFETY AND/OR EFFICACY OF SUCH  
DEVICES THE FIRMS MAY IMPORT INTO THE U.S.

3. ITINERARY AS FOLLOWS:

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OCTOBER 14, 1977 - DEPART WASHINGTON, D.C. FOR STOCKHOLM,  
SWEDEN

OCTOBER 17-21 - VISIT GAMBRO

OCTOBER 22 - TRAVEL STOCKHOLM SWEDEN TO LONDON,  
ENGLAND

OCTOBER 24-28 - VISIT PORTEX

OCTOBER 30, 1977 - TRAVEL LONDON, ENGLAND FOR WASHINGTON,  
D.C.

4. ASSISTANCE OF EMBASSIES WILL NOT BE REQUIRED. VANCE

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NNN

## Message Attributes

**Automatic Decaptoning:** X  
**Capture Date:** 01-Jan-1994 12:00:00 am  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** TECHNICAL ASSISTANCE, FOREIGN ASSISTANCE, VISITS, INSPECTIONS, BUSINESS FIRMS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Sent Date:** 16-Sep-1977 12:00:00 am  
**Decaption Date:** 01-Jan-1960 12:00:00 am  
**Decaption Note:**  
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**Disposition Approved on Date:**  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
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**Disposition Event:**  
**Disposition History:** n/a  
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**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** JRWEINROTH,M.D.:CM  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Expiration:**  
**Film Number:** D770338-0393  
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**Litigation History:**  
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**Message ID:** 0ce7ab43-c288-dd11-92da-001cc4696bcc  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
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**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**SAS ID:** 1242448  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDA REPRESENTATIVE PROVIDING TECHNICAL AND CONSULTATIVE ASSISTANCE TO FOREIGN DEVICE MANUFACTURERS  
**TAGS:** OGEN, OTRA, ETRD, EIND, TBIO, SW, UK, US, (WOLK, ANTHONY)  
**To:** STOCKHOLM LONDON  
**Type:** TE  
**vdkvgwkey:** odbc://SAS/SAS.dbo.SAS\_Docs/0ce7ab43-c288-dd11-92da-001cc4696bcc  
**Review Markings:**  
Margaret P. Grafeld  
Declassified/Released  
US Department of State  
EO Systematic Review  
22 May 2009  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009